APPLICATION FOR UNITED STATES LETTERS PATENT

FOR

SURGICAL TAPE TENSIONER

BY:

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SURGICAL TAPE TENSIONER

BACKGROUND OF THE INVENTION

5 1. Cross-Reference to Related Application:

This application claims the benefit of and priority to a U.S. Provisional Patent Application No. 60/430,602 filed December 3, 2002, the technical disclosure of which is hereby incorporated herein by reference.

10 2. Technical Field:

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The present invention relates to an improved device to tension or secure surgical tape that is used in the surgical ligation of circulatory vessels or in positioning organs and structures during surgery.

3. Description of Related Art:

During surgical procedures, there is a need to maintain a clear field of view of the affected anatomical structures for the surgeon. This can involve retracting intervening structures to one side of the operative field and stopping the leakage of blood or other fluids from their respective vessels. For tiny blood vessels that can regenerate quickly, the surgeon may choose to cauterize (seal with heat) a vessel, but with larger circulatory vessels, the surgeon must preserve the ability to restore normal circulation after surgery is completed, and will bind or ligate the vessel with surgical tape. Due to the possibility of causing injury to the circulatory vessel during the procedure, the surgical tape is preferably Retract-O-Tape® vascular loops, an air-cushioned tape that is designed to avoid injury to the vessel, and manufactured by the assignee of the current application. Examples of this tape are seen in **Figures 1A** and **2A**.

Retract-O-Tape was first disclosed in U.S. Patent 4,140,125, commonly owned by the assignee, which is hereby incorporated by reference. As seen in **Figure 1A**, the tape **100** is formed as a round, hollow, silicone tube **110** that is then sealed at both ends with a silicone plug **116**. The ambient air that becomes entrapped within the hollow core provides a cushioning effect on the anatomical structure and maintains the rounded cross-section of the tube during use.

Figure 1B shows a cross-section of the ends of the surgical tape, demonstrating the walls of the

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silicone tube 110, the hollow core 118, and the silicone plugs 116. The surgical tape is provided in different gauges for use with different size structures. Figure 2A shows the same surgical tape 200 supplied with a blunt or pointed needle 202 at one end, which allows the surgeon to ligate a vessel without dissecting the vessel away from surrounding tissues. The end opposite the needle contains a silicone plug 216 to maintain the air cushioning. Figure 2B shows a cross-section of the attachment of the needle 202 to the surgical tape 200.

Figures 3A-C show the process of a blood vessel being ligated. In Figure 3A, a hemostat 320 holds a blunt needle 302 attached to a length of surgical tape 300 as the surgeon passes the needle 302 under a blood vessel 306. The tape 300 is then passed again in the same direction under the blood vessel, as seen in Figure 3B, so that the end product, shown in Figure 3C is a vessel 306 twice wrapped with the surgical tape 300. Although the patent that disclosed the aircushioned tape also disclosed a tensioner to be used in conjunction with the tape, the tensioner was never brought to market, possibly because the tiny pieces of the tensioner could become separated and easily lost in the surgical field. Instead, a hemostat can be used to secure the free ends of the surgical tape. If the need for retraction or ligation is for a short time only, a surgical nurse may hold the hemostat, but for longer periods, the hemostat will be fastened to the surgical drapings or another object to maintain the necessary tension.

Figures 4A-D show details of the tensioner 400 disclosed in Patent 4,140,125. The tensioner is composed of two separate pieces: the first piece, a clamping jaw 410 is seen in Figure 4A in an open position. The clamping jaw 410 is made of a stiff but resilient plastic material, and is shaped to have two arms 416, 418, joined by a bendable hinge section 417. An integrally formed ridge 412 extends along a portion of the inner edge of one jaw 416 and fits into a mating groove 414 on the inner side of the opposite jaw 418 to prevent the jaws 416, 418 from laterally slipping in relation to one another when closed. Figure 4B shows the clamping jaw 410 in a closed position, along with sleeve 420, which is made of an elastomeric material. In this closed position, sleeve 420 fits over the clamping jaw 410 to hold the clamping jaw closed. Note that a circular opening 422 is formed in the area of the hinge 417.

Figure 4C shows the tensioner or clamping pad 400, formed of pieces 410 and 420, assembled with a length of surgical tape 402 running through the opening 422. Note that after assembly, a portion of each jaw 416, 418 protrudes from the enclosing sleeve 420. The tensioner 400 is shown in its anticipated use in Figure 4D. Here, a blood vessel 450, seen in cross-section,

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is held between the surgical tape 402 and the sleeve 420 of tensioner 400. One end of the tape 402 is held in the opening 422 at the hinge end of the clamping jaws, while the other end has been fed between the protruding portion of the jaws 416, 418, where it would be firmly held.

It would be desirable to have a small tensioner, such as was originally intended, to use with the surgical tape instead of using hemostats. However, it would be desirable that such a tensioner not contain further small parts that could separate and cause problems. It is further desirable that such a tensioner be easily attachable to the surgical tape, easily used, and not easily lost.

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SUMMARY OF THE INVENTION

The present invention discloses a tensioner made of a unitary piece of plastic and designed to be used with a length of surgical tape. The tensioner is preferably supplied attached to a length of surgical tape that has a needle; design features allow the tape to be tensioned around a blood vessel or other elongated structure. In use, a surgeon uses the attached needle to pass the surgical tape around a blood vessel, such as the coronary artery, then threads the needle through a hole in the tensioner, so that the blood vessel is held between the side of the tensioner and the surgical tape. To stop bleeding, the surgical tape is tightened to provide sufficient tension between the tensioner and the tape, then the tape is secured in the slot opening off the hole in the tensioner. In this manner, the blood vessel is ligated, yet the ligation device takes very little room in the surgical field.

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BRIEF DESCRIPTION OF THE DRAWINGS

The novel features believed characteristic of the invention are set forth in the appended claims. The invention itself, however, as well as a preferred mode of use, further objectives and advantages thereof, will best be understood by reference to the following detailed description of an illustrative embodiment when read in conjunction with the accompanying drawings, wherein:

Figures 1A and **1B** show an exemplary piece of surgical tape that the inventive device is designed to work with and a cross-section of the ends of that tape.

Figures 2A and 2B show another exemplary piece of surgical tape and a cross-section, this tape having a needle.

Figures 3A, 3B and, 3C demonstrate surgical tape being applied to ligate a blood vessel.

Figures 4A, 4B, 4C, and 4D show the parts and the use of a clamping pad according to the prior art.

Figure 5 is a perspective view of a tensioner according to an embodiment of the present invention.

Figure 6 shows a top view of the tensioner of Figure 5, while Figures 6A through 6D show cross-sections and a detail of the embodiment of the innovative tensioner.

Figure 7 shows a tensioner according to the present invention as it is used to ligate a blood vessel.

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DETAILED DESCRIPTION OF THE INVENTION

The description of the present invention has been presented for purposes of illustration and description, and is not intended to be exhaustive or limited to the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art. The embodiment was chosen and described in order to best explain the principles of the invention, the practical application, and to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

The present innovations are described with reference to Figures 5-7. Figure 5 shows a greatly enlarged perspective view of an innovative tensioner 500 according to the disclosed invention. The tensioner 500 has generally rounded ends and edges are beveled to reduce the chance of injury to surrounding tissue when in use. A circular opening 502 extends through the tensioner 500. This opening is sized to permit a length of surgical tape and attached needle to pass through. Slot 504 opens off of the circular opening 502, while at the opposite end of the tensioner 500, slot 506 is similarly sized. Both of these slots 504, 506 provide a tight fit through which the surgical tape will not easily move.

Figure 6 is a top down view of the tensioner of Figure 5 and shows the relative dimensions of an exemplary embodiment. The embodiment of the tensioner has an overall length of 0.310 inches and a width of 0.10 inches, with straight sides and essentially semi-circular ends. The circular opening has a diameter that is approximately one-half the width of the tensioner or 0.05 inches. Figure 6A is a cross-section, along the length of the tensioner at its midline, with shaded areas showing where cuts would be made through the material of the tensioner to achieve the section. Figure 6B shows a cross-section across the tensioner through slot 506, showing the narrow opening; Figure 6C is a cross-section across the tensioner through the center of opening 502. Figure 6D is an enlarged view of the slot 506. One can see most clearly in this view that the opening into slot 506 tapers inward to a neck 608, then opens out somewhat into the body 610 of the slot. This allows the surgical tape to be smoothly guided into the body 610, while preventing the tape from moving back out through the neck 608.

After manufacture of the tensioner, a short length of surgical tape, having an attached needle, is introduced into slot 506. Preferably the opening into slot 506 is then occluded, such as

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with a bead of adhesive. In this manner, the tensioner 500 is permanently attached to the surgical tape.

Figure 7 shows the inventive tensioner in use. In this drawing, blood vessel 706 has been ligated between tensioner 500 and surgical tape 702. The surgical tape 702 is securely held in the two slots 504, 506. Adhesive bead 710 retains the tape in slot 506.

While the disclosed design is the presently preferred embodiment of the invention, one of ordinary skill in the art will understand that many variations on this specific design are possible without departing from the spirit of the invention.

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